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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,043	04/15/2004	Mark Edward Riehl	NNI-0043	7399

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

NOTIFICATION DATE	DELIVERY MODE
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02/04/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficemonitor@woodcock.com

Office Action Summary	Application No. 10/825,043	Applicant(s) RIEHL ET AL.	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 16-35,42-58 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9,36,37,59-65,67 and 68 is/are rejected.
- 7) ☒ Claim(s) 7,10-15,38-41 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 January 2011 has been entered. Claims 1-69 are now pending. Claims 16-35, 42-58 and 69 remain withdrawn from consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6, 8, 9, 59-65, 67 and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Mechlenburg et al. (U.S. Patent No. 7,367,935). Mechlenburg et al. (hereinafter Mechlenburg) disclose a method and apparatus for a magnetic stimulation placed over the head. Regarding claims 1-3, 9, 59-62 and 68, Mechlenburg teaches a

system comprising: a magnetic stimulation coil **56** (capable of functioning as a TMS coil) having two treatment faces (Fig. 4) for treating a patient; a pulse generating device **32** that applies pulses to the coil (col. 4, lines 48-67 and col. 16, lines 18-27); a sensor **62** (or plurality thereof as noted at col. 5, lines 7-22), disposed in a flexible collar (col. 6, lines 63-66), for detecting contact between the coil and the patient, the sensor disposed between the coil and a position at which pulses are applied (Fig. 3); and signal processing circuitry that processes outputs of the sensor to provide indication of coil placement with respect to the position at which pulses are applied, and furthermore whether the treatment faces are disposed at the position (col. 17, lines 53-62).

Regarding claims 4 and 63, the signal processing circuitry can detect the device when the device is disposed on the patient (col. 17, lines 53-62). Regarding claims 5, 6, 8, 64, 65 and 67, signals indicative of the magnetic stimulator (and therefore the coil) being properly positioned can be provided to a display unit such as a monitor. An alarm or visual warning **41a**, **41b** may be generated if the collar (housing the coil) has been removed from the patient, therefore providing an indication to move the coil into the position in the event that the coil has been removed from the position (col. 5, lines 38-67 - col. 5, lines 1-5).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (U.S. Pub. No. 2001/0002441). Boveja discloses the invention as claimed, to include a substrate disposed between a coil and a position of a patient and at least one sensor for detecting contact between the coil and the patient, the sensor disposed on the substrate to detect proximity of the coil to a position using a magnetic field (Fig. 7 and [0051]); however Boveja does not disclose expressly that the sensor is disposed in a flexible substrate. Instead, Boveja indicates that the sensor or sensing unit contained in the coil is taped firmly to the skin for efficient energy transfer to occur [0051]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a flexible substrate because Applicant has not disclosed that a flexible substrate provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Boveja's stimulation system and applicant's invention, to perform equally well with either the substrate taught by Boveja or the claimed flexible substrate because both would perform the same function of enabling conformation to the skin of a patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Boveja to obtain the invention as specified in claim 36 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Boveja.

6. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (U.S. Pub. No. 2001/0002441) in view of Grove et al. (U.S. Pub. No. 2004/0167592).

Boveja discloses the invention as claimed, see rejection supra; however Boveja does not disclose a membrane switch. Grove et al. (hereinafter Grove) teaches an apparatus which employs a therapeutic energy source and one or more switches placed in contact with a person's skin. Regarding claim 37, Grove discloses that a contact sensor, as similarly taught by Boveja, may be a type of membrane switch such that when the apparatus is pressed against the skin, the membrane switch closes, indicating the initiation of pulsing therapy [0016]. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated membrane switches as disclosed by Grove into a therapeutic pulsing apparatus as taught by Boveja for indicating contact with a patient's skin and subsequently initiating therapy.

Moreover, the combination of Boveja in view of Grove discloses the invention as claimed, see rejection supra; however the combination does not disclose expressly that the membrane switch comprises respective conducting films separated by a dielectric layer. Instead, Boveja in view of Grove discloses that a contact sensor may be a type of membrane switch such that when the apparatus is pressed against the skin, the membrane switch closes, indicating the initiation of pulsing therapy [0016]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a membrane switch comprising respective conducting films separated by a dielectric layer because Applicant has not disclosed that such a membrane switch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Boveja in view of Grove's stimulation system and applicant's invention, to perform equally well

with either the membrane switches taught by Boveja in view of Grove or the claimed membrane switch comprising respective conducting films separated by a dielectric layer because both would perform the same function of sensing positioning and contact with the skin of the patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Boveja in view of Grove to obtain the invention as specified in claim 37 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Boveja in view of Grove.

Allowable Subject Matter

7. Claims 7, 10-15, 38-41 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 7, while the prior art teaches a display device for indication of a position of the coil, the prior art of record does not teach or fairly suggest a TMS system as claimed by Applicant, wherein the display device presents a pressure map indicating whether the coil has proper contact at the position and where the coil does not have proper contact at the position.

Regarding claims 10-15, the prior art of record does not teach or fairly suggest: a TMS system for providing treatment to a patient comprising: a TMS coil for treating the patient using a magnetic field; a pulse generating device that applies pulses to the coil

during TMS treatment; a sensor disposed between the coil and a position at which pulses are applied, the sensor detecting proximity of the coil to the position; signal processing circuitry that processes output from the sensor to provide an indication of whether the coil is properly disposed with respect to the position receiving pulse therapy from the coil; wherein the sensor comprises at least one sensor disposed in or on a flexible substrate that is located between the coil and the position at which pulses are applied to determine if the coil is properly positioned, wherein at least one sensor comprises membrane switches that change state when depressed, each switch comprising respective conductive films separated by a dielectric layer.

Regarding claims 38-41, the prior art of record does not teach or fairly suggest a device that detects proximity of a TMS coil to a position of a patient during TMS treatment using a magnetic field, comprising: a flexible substrate disposed between the coil and the position; at least one sensor disposed on the substrate in order to detect proximity of the coil to the position; wherein at least one sensor comprises membrane switches that change state when depressed, each switch comprising respective conductive films separated by a dielectric layer; wherein the conductive films have a sufficient resistance so as to reduce eddy currents.

Regarding claim 66, while the prior art teaches a method for the indication of a position of the coil on display, the prior art of record does not teach or fairly suggest a method of providing TMS treatment as claimed by Applicant, wherein the display device presents a pressure map indicating whether the coil has proper contact at the position and where the coil does not have proper contact at the position.

Response to Arguments

8. Applicant's arguments filed 26 January 2011 with respect to the rejection of claims 1-6, 8, 9, 59-65, 67 and 68 under 35 U.S.C. 102(e) citing Mechlenburg ('935) have been fully considered and are not persuasive. Applicant contends that Mechlenburg does not provide an indication whether a treatment coil is properly disposed on the patient with respect to any particular position based on the sensor output. However, this argument is not persuasive. Applicant's attention is directed to col. 17, lines 53-60 whereby sensors on the collar detect when the device is disposed on the patient. The output of these sensors is used to control the actuation and deactivation of stimulation therapy. An alarm provides an indication as to whether or not the patient has removed or put on the collar (col. 5, lines 38-47). Applicant further contends that the sensors in Mechlenburg detect temperatures, but not contact between a coil used for treatment and a position at which pulses are applied. However, this argument is not persuasive as the sensors, whether temperature-responsive or not, indicate proper positioning or removal of the treatment device. Applicant also contends that Mechlenburg does not teach that the sensors are disposed between the coil and a position at which pulses are applied. However, this argument is not persuasive. Sensor **62** is disposed between coil **56** and a position at which pulses are applied (sternothyroid **46**, sternohyoid **42** and thyroid **44** muscles) as shown in Fig. 3. In view of the foregoing, the rejection of claims 1-6, 8, 9, 59-65, 67 and 68 under 35 U.S.C. 102(e) citing Mechlenburg ('935) has been maintained.

9. Applicant's arguments filed 26 January 2011 with respect to the rejection of claim 36 under 35 U.S.C. 103(a) citing Boveja (U.S. Pub. No. 2001/0002441) and claim 37 U.S.C. 103(a) citing Boveja (U.S. Pub. No. 2001/0002441) in view of Grove ('592) have been fully considered and are not persuasive. Applicant contends that Boveja does not disclose the use of a coil for treatment of a patient using a magnetic field. However, this argument is not persuasive. The claim only recites a device that detects proximity of a coil during treatment of a patient *"using a magnetic field."* The claim does not positively recite application of a magnetic field, rather it cites the intended use of such a device. Furthermore, Applicant's argument that the coils are not treatment components is not persuasive because, again, this only cites the intended use of the coils. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The coils are fully capable of being utilized as TMS coils.

Applicant also contends that the sensors of Boveja do not detect contact between the coil and the patient. However, this argument is not persuasive given the fact that the sensors indicate location based on measured parameters of the field from a magnet contained in the coil. Therefore, the sensor is still fully capable of sensing contact, as it is capable of sensing location. Applicant further contends that Boveja does not teach a sensor that is disposed between a TMS coil and a position at which pulses are applied, however such a limitation is not recited in the claims.

In view of the foregoing, the rejection of claim 36 under 35 U.S.C. 103(a) citing Boveja (U.S. Pub. No. 2001/0002441) and claim 37 under U.S.C. 103(a) citing Boveja (U.S. Pub. No. 2001/0002441) in view of Grove ('592) has been maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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